

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:5648
ANSWERED ON:16.05.2007
CLINICAL TRIALS BY MNCS
Ajaya Kumar Shri S.;Singh Shri Chandra Bhushan

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the some multinational companies have been conducting clinical trials in India in view of stringent law in many European countries;
- (b) if so, the details thereof and the reasons therefor;
- (c) whether the Government proposes to enact a law with regard to clinical trials in the country;
- (d) if so, the details thereof; and
- (e) if not, the reasons therefor?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) & (b) It is not a fact that stringent laws in Europe and other countries have driven these multinational companies to India for clinical trials.

India has some inherent and natural advantages in clinical research. India's highly skilled medical fraternity, many world class medical institutions, a large treatment naïve population, and the cost competitive of Indian research institutions gives India a definite advantage over other countries in the matter of Clinical Research.

(c) to (e) Regulation for conducting Clinical Trials in the country are prescribed under Rules 122 DA-122 E and Schedule Y of Drugs & Cosmetics Rules which was amended in the year 2005.

Good Clinical Practices (GCP) Guidelines were introduced by the Ministry in the year 2001 and Ethical Guidelines for Biomedical Research were issued by Indian Council of Medical Research (ICMR) in the year 2000.